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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,570	09/27/2001	Toshiya Kai	NPR-085	8923

20374 7590 06/04/2002

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

2113

Office Action Summary

Application No.

09/963,570

Applicant(s)

KAI ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a solid preparation, classified in class 424, subclass 677.
- II. Claims 8-9, drawn to a process for producing a solid preparation, classified in class 424, subclass 490 .

The inventions are distinct, each from the other because:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make a different and distinct product, such as a solid preparation containing coated particles versus a solid preparation containing uncoated particles as seen in claim 1 of invention I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Kubovcik on May 30, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this

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Office action. Claims 8-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of co-pending Application No. 09/963550.

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 recites a solid preparation containing particles from two composition and an acid, which encompasses claim 1 of co-pending application 09/963550. Instant claim 4 recites, "wherein the acid is acetic acid, hydrochloric acid or lactic acid." Claim 2 of co-pending application recites the same acids. Instant claim 6 and co-pending application claim 3 recite the same particle sizes. Instant claim 7 and claim 4 of co-pending application recite the inclusion of sodium carbonate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a first composition and “particles of a second composition containing a sugar, and an acid.” The examiner is unclear whether the second composition contains sugar and acid or the second composition contains only sugar.

Claim 3 recites, “second composition comprises core particles comprising particles of a sugar, the core particles being covered with a coating layer comprising said sugar or different sugar.” The examiner is unclear how said sugar can be coated with said sugar and be considered distinct in that there is a core and a coating.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Veltman (4756838).

Veltman discloses a dry dialysate product containing instant electrolytes (Note examples, esp. example 7). Veltman discloses a sodium bicarbonate system and a sodium acetate system (col. 5, lines 15-25, examples). Depending if the patient requires dextrose, it may be added either to the dialysis solution or anhydrous dextrose can be mixed to the dry dialysate preparation (col. 10, lines 10-19, examples 9-10). Veltman discloses that dextrose is frequently a component of dialysis solutions, however the amount of dextrose varies from patient to patient (col. 7, lines 10-30). Further, Veltman discloses core particles coated by electrolytes (example 13). Lastly, the reference discloses the addition of acid (HCl and acetic acid) to lower the pH of the solution and slow down precipitation of the electrolytes (col. 45-66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veltman (4756838).

As set forth above, Veltman discloses a dry dialysate product containing instant electrolytes (Note examples, esp. example 7). Veltman discloses a sodium bicarbonate system and a sodium acetate system (col. 5, lines 15-25, examples). Depending if the patient requires dextrose since all patient do not require it, it may be added either to the dialysis solution or anhydrous dextrose can be mixed to the dry dialysate preparation

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(col. 10, lines 10-19, examples 9-10). Veltman discloses that dextrose is frequently a component of dialysis solutions, however the amount of dextrose varies from patient to patient (col. 7, lines 10-30). Further, Veltman discloses core particles coated by electrolytes (example 13). Lastly, the reference discloses the addition of acid (HCl and acetic acid) to lower the pH of the solution and slow down precipitation of the electrolytes (col. 45-66).

Assuming Veltman is not considered to anticipate the instant invention due to the indefiniteness of the claims, Veltman is deemed obvious to one of ordinary skill in the art to modify Veltman's dry dialysate, depending on the requirements of the patient (as defined above).

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

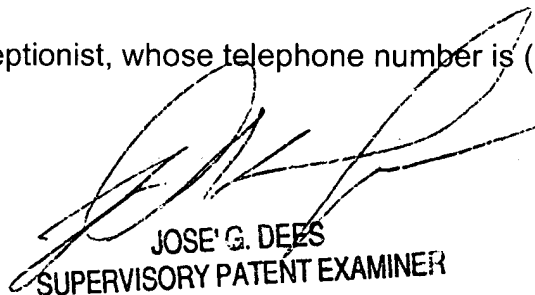
If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG



May 31, 2002



JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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